

ORIGINAL

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12 d/b/a GLAXOSMITHKLINE

FILED

MAY 27 2008

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA

15 DORIS E. SECORD, RAYMOND
16 SEXTON, LINDA L. SHELTON,
17 MADELINE SHERRILL, LEONARD M.
18 SHULL, WANDA F. SPANGLER,
19 KENNETH W. SPEARS, VENIDA
20 SPENCE, VICTOR BRENT STEPHENS,
21 LORETTA STURGILL, BOBBY
22 TACKER, MARTHA TATE, PEGGY
23 TAYLOR, LILLIAN THACKER, JANET
24 THARPE, REBECCA J. THREEWIT,
25 HUBERT TOLLETT, COY VADEN,
26 WILLIS VANCE, KYLE WARREN,

Plaintiffs,

17 v.
18
19 SMITHKLINE BEECHAM
20 CORPORATION d/b/a
21 GLAXOSMITHKLINE and MCKESSON
22 CORPORATION,

Defendants.

Case No. 08-25

NOTICE OF REMOVAL AND
REMOVAL ACTION UNDER 28 U.S.C.
§ 1441(B) (DIVERSITY) and 28 U.S.C. §
1441(C) (FEDERAL QUESTION) OF
DEFENDANT SMITHKLINE
BEECHAM CORPORATION d/b/a
GLAXOSMITHKLINE

24 TO THE CLERK OF THE COURT:

25 Defendant Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"),
26 hereby removes to this court the state action described below. Removal is warranted
27 under 28 U.S.C. § 1441 because this is an action over which this Court has original
28 jurisdiction under 28 U.S.C. §§ 1331 and 1332.

1 **I. BACKGROUND**

2 1. On May 21, 2008, Plaintiffs Doris Second, Raymond Sexton, Linda
 3 Shelton, Madeline Sherrill, Leonard Shull, Wanda Spangler, Kenneth Spears, Venida
 4 Spence, Victor Stephens, Loretta Sturgill, Bobby Tacker, Martha Tate, Peggy Taylor,
 5 Lillian Thacker, Janet Tharpe, Rebecca Threewit, Hubert Tollett, Coy Vaden, Willis
 6 Vance, and Kyle Warren, ("Plaintiffs"), represented by The Miller Firm of Orange,
 7 Virginia, commenced this action in the Superior Court of the State of California for the
 8 County of San Francisco. A true and correct copy of the Complaint in the action is
 9 attached as Exhibit "A" to the Declaration of Krista L. Cosner in Support of Notice of
 10 Removal and Removal Action under 28 U.S.C. § 1441(b) and 28 U.S.C. § 1441(c)
 11 (Federal Question) of Defendant SmithKline Beecham Corporation dba GlaxoSmithKline
 12 (hereinafter "Cosner Decl.").

13 2. Neither defendant has yet been served with Plaintiffs' Complaint. Cosner
 14 Decl. ¶9.

15 3. There have been no additional proceedings in the state court action.

16 4. This is one of many cases that have been filed recently in both federal and
 17 state court across the country involving the prescription drug Avandia®. Cosner Decl. ¶
 18 5. Plaintiffs' counsel, The Miller Firm, has filed Avandia cases in both state and federal
 19 courts, but only in the cases filed in California has The Miller Firm named McKesson, or
 20 any alleged distributor of Avandia, as a defendant. Cosner Decl. ¶6.

21 5. On October 16, 2007, the Judicial Panel on Multidistrict Litigation
 22 ("JPML") issued an order directing that then-pending Avandia-related cases be
 23 transferred and coordinated for pretrial proceedings in the United States District Court for
 24 the Eastern District of Pennsylvania, before the Honorable Cynthia M. Rufe, pursuant to
 25 28 U.S.C. § 1407. *See Transfer Order, In re Avandia Marketing, Sales Practices and*
 26 *Products Liability Litigation*, MDL 1871 (E.D.P.A.) (a true and correct copy of which is
 27 attached as Exhibit "B" to Cosner Decl.). Additional Avandia-related cases pending in
 28 federal court, which are common to the actions previously transferred to the Eastern

1 District of Pennsylvania and assigned to Judge Rufe, are treated as potential tag-along
 2 actions. *See id.; see also* Rules 7.4 and 7.5, R.P.J.P.M.L. 199 F.R.D. 425, 435-36 (2001).
 3 GSK intends to seek the transfer of this action to that Multidistrict Litigation, *In re*
 4 *Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL 1871, and
 5 shortly will provide the JPML with notice of this action pursuant to the procedure for
 6 “tag along” actions set forth in the rules of the JPML. Cosner Decl. ¶7.

7 6. As more fully set forth below, this case is properly removed to this Court
 8 pursuant to 28 U.S.C. § 1441 because GSK has satisfied the procedural requirements for
 9 removal and this Court has subject matter jurisdiction over this case pursuant to 28
 10 U.S.C. §§ 1331 and 1332.

11 **II. DIVERSITY JURISDICTION**

12 7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332
 13 because this is a civil action in which the amount in controversy exceeds the sum of
 14 \$75,000, exclusive of costs and interest, and is between citizens of different states.

15 **A. There is Complete Diversity of Citizenship Between Plaintiffs and**
 16 **Defendants**

17 8. The Complaint names twenty individual plaintiffs. *See* Cosner Decl., Exh.
 18 A, ¶¶ 10-29:

19 a. Plaintiff Doris Secord alleges that she is a “resident” of the State of
 20 Kentucky. Accordingly, at the time this action was commenced, she was a citizen of the
 21 State of Kentucky. *Id.* at ¶ 10.

22 b. Plaintiff Raymond Sexton alleges that he is a “resident” of the State
 23 of Kentucky. Accordingly, at the time this action was commenced, he was a citizen of
 24 the State of Kentucky. *Id.* at ¶ 11.

25 c. Plaintiff Linda Shelton alleges that she is a “resident” of the State of
 26 Tennessee. Accordingly, at the time this action was commenced, she was a citizen of the
 27 State of Tennessee. *Id.* at ¶ 12.

28 d. Plaintiff Madeline Sherrill alleges that she is a “resident” of the State

1 of Kentucky. Accordingly, at the time this action was commenced, she was a citizen of
 2 the State of Kentucky. *Id.* at ¶ 13.

3 e. Plaintiff Leonard Shull alleges that he is a “resident” of the State of
 4 Kentucky. Accordingly, at the time this action was commenced, he was a citizen of the
 5 State of Kentucky. *Id.* at ¶ 14.

6 f. Plaintiff Wanda Spangler alleges that she is a “resident” of the State
 7 of Kentucky. Accordingly, at the time this action was commenced, she was a citizen of
 8 the State of Kentucky. *Id.* at ¶ 15.

9 g. Plaintiff Kenneth Spears alleges that he is a “resident” of the State of
 10 Kentucky. Accordingly, at the time this action was commenced, he was a citizen of the
 11 State of Kentucky. *Id.* at ¶ 16.

12 h. Plaintiff Venida Spence alleges that she is a “resident” of the State
 13 of Kentucky. Accordingly, at the time this action was commenced, she was a citizen of
 14 the State of Kentucky. *Id.* at ¶ 17.

15 i. Plaintiff Victor Brent Stephens alleges that he is a “resident” of the
 16 State of Kentucky. Accordingly, at the time this action was commenced, he was a citizen
 17 of the State of Kentucky. *Id.* at ¶ 18.

18 j. Plaintiff Loretta Sturgill alleges that she is a “resident” of the State
 19 of Kentucky. Accordingly, at the time this action was commenced, she was a citizen of
 20 the State of Kentucky. *Id.* at ¶ 19.

21 k. Plaintiff Bobby Tacker alleges that he is a “resident” of the State of
 22 Tennessee. Accordingly, at the time this action was commenced, he was a citizen of the
 23 State of Tennessee. *Id.* at ¶ 20.

24 l. Plaintiff Martha Tate alleges that she is a “resident” of the State of
 25 Tennessee. Accordingly, at the time this action was commenced, she was a citizen of the
 26 State of Tennessee. *Id.* at ¶ 21.

27 m. Plaintiff Peggy Taylor alleges that she is a “resident” of the State of
 28 Tennessee. Accordingly, at the time this action was commenced, she was a citizen of the

1 State of Tennessee. *Id.* at ¶ 22.

2 n. Plaintiff Lillian Thacker alleges that she is a “resident” of the State
3 of Kentucky. Accordingly, at the time this action was commenced, she was a citizen of
4 the State of Kentucky. *Id.* at ¶ 23.

5 o. Plaintiff Janet Tharpe alleges that she is a “resident” of the State of
6 Tennessee. Accordingly, at the time this action was commenced, she was a citizen of the
7 State of Tennessee. *Id.* at ¶ 24.

8 p. Plaintiff Rebecca Threewit alleges that she is a “resident” of the
9 State of Tennessee. Accordingly, at the time this action was commenced, he was a
10 citizen of the State of Tennessee. *Id.* at ¶ 25.

11 q. Plaintiff Hubert Tolett alleges that he is a “resident” of the State of
12 Tennessee. Accordingly, at the time this action was commenced, he was a citizen of the
13 State of Tennessee. *Id.* at ¶ 26.

14 r. Plaintiff Coy Vaden alleges that he is a “resident” of the State of
15 Kentucky. Accordingly, at the time this action was commenced, he was a citizen of the
16 State of Kentucky. *Id.* at ¶ 27.

17 s. Plaintiff Willis Vance alleges that he is a “resident” of the State of
18 Kentucky. Accordingly, at the time this action was commenced, he was a citizen of the
19 State of Kentucky. *Id.* at ¶ 28.

20 t. Plaintiff Kyle Warren alleges that he is a “resident” of the State of
21 Tennessee. Accordingly, at the time this action was commenced, he was a citizen of the
22 State of Tennessee. *Id.* at ¶ 29.

23 9. GSK is, and was at the time Plaintiffs commenced this action, a corporation
24 organized under the laws of the Commonwealth of Pennsylvania with its principal place
25 of business in Philadelphia, Pennsylvania, and therefore, is a citizen of Pennsylvania for
26 purposes of determining diversity. 28 U.S.C. § 1332(c)(1). Cosner Decl. ¶8.

27 10. The remaining named defendant, McKesson, is a Delaware corporation,
28 with its principal place of business in San Francisco, California. Cosner Decl., Exh. C

1 ¶3. Accordingly, there is complete diversity of citizenship between plaintiffs and
 2 defendants.

3 **B. The Amount In Controversy Requirement Is Satisfied**

4 11. It is apparent on the face of the Complaint that Plaintiffs seek an amount in
 5 controversy in excess of \$75,000, exclusive of costs and interest.

6 12. Plaintiffs allege that they ingested Avandia, and, as a result, "have suffered
 7 heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure,
 8 stroke and severe injury to the heart leading to cardiac arrest," and have sustained,
 9 "physical and financial damages including pain and suffering." *See Cosner Decl. Exh. A*
 10 at ¶ 52. Plaintiffs further allege that Plaintiffs "suffered severe and permanent physical
 11 injuries" and endured substantial pain and suffering and extensive medical and surgical
 12 procedures." *See id.* at ¶ 69.

13 13. Plaintiffs allege that they have suffered economic loss, and have otherwise
 14 been physically, emotionally and economically injured, and that their injuries and
 15 damages are permanent and will continue into the future. *See Cosner Decl. Exh. A, ¶ 69.*

16 14. Plaintiffs seek actual and punitive damages. *See Cosner Decl. Exh. A,*
 17 Prayer for Relief.

18 15. Punitive damages are included in the calculation of the amount in
 19 controversy. *See Bell v. Preferred Life Assurance Society*, 320 U.S. 238, 240 (1943).

20 16. Given the allegations set forth above, the face of the Complaint makes clear
 21 that Plaintiffs seek in excess of \$75,000, exclusive of interest and costs. *See Simmons v.*
 22 *PCR Tech.*, 209 F. Supp. 2d 1029, 1031 (N.D. Cal. 2002).

23 **C. The Citizenship of McKesson Must Be Ignored Because**
 24 **McKesson Has Not Been Properly Joined and Served**

25 17. Under 28 U.S.C. § 1441(b), the so-called "forum defendant rule," an action
 26 is removable only if none of the parties in interest, *properly joined and served as*
 27 defendants, is a citizen of the State in which such action is brought. 28. U.S.C § 1441(b)
 28 (emphasis added).

1 18. McKesson, although a citizen of California, has not yet been served with
 2 the Complaint in this case.

3 19. Accordingly, because there is complete diversity of citizenship and because
 4 no “properly joined and served defendant” is a citizen of this State, it is appropriate that
 5 this action be removed to this Court. *See Waldon v. Novartis Pharmaceuticals Corp.*,
 6 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007); *see also* 28 U.S.C. § 1441(b).

7 **D. The Citizenship Of McKesson Must Be Ignored Because**
 8 **McKesson Is Fraudulently Joined**

9 20. A defendant is fraudulently joined, and its presence in the lawsuit is
 10 ignored for purposes of determining the propriety of removal, “if the plaintiff fails to
 11 state a cause of action against the resident defendant, and the failure is obvious according
 12 to the settled rules of the state.” *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067
 13 (*9th Cir. 2001*); *see also Hamilton Materials, Inc. v. Dow Chemical Corporation*, 494
 14 F.3d. 1203, 1206 (*9th Cir. 2007*).

15 21. McKesson is fraudulently joined because Plaintiffs have failed to make any
 16 specific material allegations against it. Plaintiffs do not even allege that they ingested
 17 Avandia that was distributed by McKesson, compelling the conclusion that Plaintiffs
 18 have fraudulently joined McKesson in an attempt to defeat diversity jurisdiction. *See*,
 19 *e.g., Brown v. Allstate Insur.*, 17 F. Supp. 2d 1134, 1137 (*S.D. Cal. 1998*) (finding in-
 20 state defendants fraudulently joined where “no material allegations against [the in-state
 21 defendants] are made”); *Lyons v. American Tobacco Co.*, No. Civ. A. 96-0881-BH-S,
 22 1997 U.S. Dist. LEXIS 18365 (*S.D. Ala. 1997*) (holding that there is “no better admission
 23 of fraudulent joinder of [the resident defendant]” than the failure of the plaintiff “to set
 24 forth any specific factual allegations” against them). Plaintiffs cannot cure this
 25 deficiency by simply relying on allegations directed toward “Defendants” or GSK alone.

26 22. Plaintiffs specifically allege that GSK was engaged in the business of
 27 designing, developing, manufacturing, testing, packaging, promoting, marketing,
 28 distributing, labeling and/or selling Avandia. *See* Cosner Decl. Exh. A, at ¶ 31. Further,

1 plaintiffs specifically allege that Avandia was created and marketed by GSK; that GSK
 2 had longstanding knowledge of Avandia-related dangers which GSK failed to adequately
 3 warn and disclose to consumers; that GSK concealed, suppressed and failed to disclose
 4 these referenced dangers; that GSK has represented and has continued to represent that it
 5 manufactures and/or sells safe and dependable pharmaceuticals; that GSK has failed to
 6 adequately warn or inform consumers, such as Plaintiffs or Plaintiffs' prescribing
 7 physicians of known defects in Avandia; and that as a result of GSK's omissions and/or
 8 misrepresentations, Plaintiffs ingested Avandia. *See id.* at ¶¶ 40, 44-46, 49 & 51.

9 23. Plaintiffs also claim, however, that McKesson "packaged, distributed,
 10 supplied, sold, placed into the stream of commerce, labeled, described, marketed,
 11 advertised, promoted and purported to warn or inform users regarding the risks pertaining
 12 to, and assuaged concerns about [] Avandia." *See id.* at ¶ 38. These allegations are
 13 inconsistent and contradictory, and courts have frequently viewed such inconsistencies as
 14 evidence of fraudulent joinder. *See Baisden v. Bayer Corp.*, 275 F. Supp. 2d 759, 762-
 15 763. (S.D. W.Va. 2003).

16 24. Plaintiffs assert claims of: (1) negligence; (2) negligent failure to
 17 adequately warn; (3) negligence per se; (4) negligent misrepresentation; (5) breach of
 18 express warranty; (6) breach of implied warranty; (7) strict products liability – defective
 19 design; (8) strict products liability – manufacturing and design defect; (9) strict products
 20 liability – failure to adequately warn; (10) fraudulent misrepresentation; (11) violations of
 21 California Unfair Trade Practices and Consumer Protection Law; (12) unjust enrichment;
 22 (13) loss of consortium and (14) punitive damages. In these allegations, Plaintiffs aver
 23 that collectively, "Defendants" or "Defendants GSK and McKesson," defectively
 24 designed and manufactured the product; concealed knowledge of unreasonably dangerous
 25 risks associated with the product; failed to conduct adequate and sufficient pre-clinical
 26 testing and post-marketing surveillance of the product; failed to provide FDA with
 27 complete and adequate information regarding the product; failed to warn consumers
 28 and/or their health care providers of certain risks associated with the product; failed to

1 utilize adequate and non-misleading labeling; and made affirmative misrepresentations
 2 and omissions regarding the risks associated with taking Avandia. All of these claims are
 3 substantively based on the design and manufacture of the product, failure to warn,
 4 fraudulent concealment, and inadequate pre-clinical testing and post-marketing
 5 surveillance. As a wholesale distributor of Avandia, McKesson played no role in its
 6 testing, marketing or advertising. All McKesson did was pass along unopened boxes of
 7 Avandia, in unadulterated form, to hospitals and other businesses in the healthcare
 8 industry. *See* Cosner Decl. Exh. C, ¶¶ 6-7.¹

9 25. Further, based on the “learned intermediary” doctrine, McKesson bore no
 10 duty to warn Plaintiffs. The “learned intermediary” doctrine, the foundation of
 11 prescription drug product liability law, provides that the duty to warn about a drug’s risks
 12 runs from the manufacturer to the physician (the “learned intermediary”), and then from
 13 the physician to the patient. *See Brown v. Superior Court (Abbott Labs.)*, 44 Cal. 3d
 14 1049, 1061-62, n.9 (1988); *Carlin v. Superior Court (Upjohn Co.)*, 13 Cal. 4th 1104, 1116
 15 (1996). It is the physician, and only the physician, who is charged with prescribing the
 16 appropriate drug and communicating the relevant risks to the patient. *See Brown*, 44 Cal.
 17 3d at 1061-62.

18 26. GSK and the FDA prepared the information to be included with the
 19 prescription drug, Avandia, with the FDA having final approval of the information that
 20 could be presented. Once the FDA has determined the form and content of the
 21 information, it is a violation of federal law to augment the information. *See* 21 U.S.C.
 22 §331(k) (prohibiting drug manufacturers and distributors from causing the “alteration,
 23

24 1 The Declaration of McKesson’s representative, Greg Yonko may be considered by the Court in
 25 determining whether McKesson is fraudulently joined. *Maffei v. Allstate California Ins. Co.*, 412
 26 F.Supp.2d 1049 (E.D. Cal. 2006) (“[t]he court may pierce the pleadings, consider the entire record, and
 27 determine the basis of joinder by any means available”) *citing Lewis v. Time, Inc.*, 83 F.R.D. 455 (E.D.
 28 Cal. 1979) (“it is well settled that upon allegations of fraudulent joinder...federal courts may look beyond
 the pleadings to determine if the joinder...is a sham or fraudulent device to prevent removal”). *See also*
Ritchey v. Upjohn Drug Co., 139 F.3d 1313, 1318-19 (9th Cir. 1998) (evidence may be presented by the
 removing party that there is no factual basis for the claims pleaded against the local defendant).

1 mutilation, destruction, obliteration, or removal of the whole or any part of the labeling”
 2 of an FDA-approved drug held for sale); *Brown v. Superior Court*, 44 Cal.3d 1049, 1069
 3 n.12 (noting that the FDA regulates the testing, manufacturing, and marketing of drugs,
 4 including the content of their warning labels). Therefore, any safety and warning
 5 information McKesson had about Avandia would have come from GSK in the form of
 6 FDA-approved packaging and labeling. McKesson could not change the labeling it was
 7 given by GSK as approved by the FDA without violating federal law. No duty can be
 8 found where it requires a party to violate the law to fulfill it.

9 27. As such, given the lack of a causal connection between the injuries alleged
 10 by Plaintiffs and McKesson’s conduct, as well as the absence of any legal or factual basis
 11 for Plaintiffs’ claims against McKesson, McKesson’s joinder is fraudulent and its
 12 citizenship should be ignored for purposes of determining the propriety of removal.

13 **III. FEDERAL QUESTION JURISDICTION**

14 28. This Court has federal question jurisdiction over Plaintiffs’ claims under
 15 28 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v.*
 16 *Darue Eng’g & Mfg.*, 125 S. Ct. 2363 (2005).

17 29. As more fully explained below, Plaintiffs have made violations of federal
 18 law critical elements of several of their claims.

19 A. **Plaintiffs’ Claims Require Construction and Application of the**
 20 **FDCA and Its Implementing Regulations**

21 30. Count III of Plaintiffs’ Complaint, “Negligence Per Se,” explicitly alleges
 22 that defendants violated federal law. Plaintiffs claim, *inter alia*, that “[d]efendants
 23 “violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301 *et seq.*,
 24 related amendments and codes and federal regulations provided thereunder, and other
 25 applicable laws, statutes, and regulations.” See Cosner Decl. Exh A, ¶ 73.

26 31. Plaintiffs further claim that “[d]efendants’ acts constituted an adulteration
 27 and/or misunderstanding *[sic]* as defined by the Federal Food, Drug and Cosmetic Act,
 28 21 U.S.C. § 331. . . .” See Cosner Decl. Exh A, ¶ 75.

1 32. Moreover, Count II of the Plaintiffs' Complaint, "Negligent Failure to
 2 Adequately Warn," and Count IX, "Strict Products Liability – Failure to Adequately
 3 Warn," also require construction and application of the FDCA and implementing federal
 4 regulations, which govern approval of prescription drugs and regulate prescription drug
 5 manufacturers' public and promotional statements, including all aspects of warnings and
 6 labeling.

7 33. As a currently-marketed prescription drug, Avandia is subject to extensive
 8 regulation by the FDA. The FDCA requires the FDA to ensure that "drugs are safe and
 9 effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and
 10 officially reviewing clinical research and taking appropriate action on the marketing of
 11 regulated products." 21 U.S.C. § 393(b)(1). The Secretary of the FDA has the authority
 12 to promulgate regulations to enforce the FDCA, which are codified in the *Code of*
 13 *Federal Regulations*, 21 C.F.R. § 200, *et seq.* See 21 U.S.C. § 371(a).

14 34. To accomplish its purpose, the FDA maintains a Center for Drug
 15 Evaluation and Research (the "CDER"). The CDER regulates pharmaceutical
 16 companies' development, testing and research, and manufacture of drugs. The CDER
 17 examines data generated by these companies to conduct a risk/benefit analysis and make
 18 an approval decision. The CDER also ensures truthful advertising for prescription drugs,
 19 in part by approving Package Inserts that properly outline benefit and risk information.
 20 Once drugs are marketed, the CDER continues to monitor them for unexpected health
 21 risks that may require public notification, a change in labeling, or removal of the product
 22 from the market. In short, the CDER evaluates and monitors the effectiveness and safety
 23 of prescription drugs. See <http://www.fda.gov/cder/about/faq/default.htm>.

24 35. Promotional communications to physicians about Avandia are contained
 25 within, and restricted by, warning, labeling, and promotional materials, such as the
 26 Package Insert, that are approved and monitored by the FDA to ensure the provision of
 27 accurate information about the drug's respective risks and benefits. Under federal
 28 regulations, even claims in promotional labeling or advertising must be consistent with

1 approved labeling. 21 C.F.R. § 202.1(e)(4) (2005).

2 36. The FDA's responsibility to regulate prescription drugs sold in the United
 3 States, and to enforce laws with respect to such drugs, inclusive of the precise content
 4 and format of prescription drug labeling (*e.g.*, the instructions, warning, precautions,
 5 adverse reaction information provided by manufacturers, and marketing materials), is
 6 plenary and exclusive. *See* 21 U.S.C. § 301, *et seq*

7 37. Plaintiffs have explicitly alleged violations of federal law in their
 8 "Negligence Per Se" claim, and have made alleged violations of federal law a critical
 9 element of their "Negligent Failure to Adequately Warn" and "Strict Products Liability –
 10 Failure to Adequately Warn" claims. Accordingly, Plaintiffs' claims necessarily raise
 11 substantial federal questions by requiring the Court to construe and apply the FDCA and
 12 its implementing regulations.

13 **B. Federal Control of Drug Labeling and Warning**

14 38. On January 24, 2006, the FDA announced a rule that includes a detailed
 15 and emphatic statement of the FDA's intention that its regulation and approval of
 16 prescription drug labeling preempt most state law claims related to the adequacy of
 17 prescription drug warnings because such claims frustrate "the full objectives of the
 18 Federal law." *See Requirements on Content and Format of Labeling for Human*
 19 *Prescription Drug and Biologic Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA
 20 believes that under existing preemption principles, FDA approval of labeling under the
 21 act. . . . preempts conflicting or contrary State law."). *See also In re Bextra and*
 22 *Celebrex Marketing*, 2006 WL 2374742 (N.D. Cal., August 16, 2006) (Celebrex
 23 decision); *In re Bextra and Celebrex Marketing*, 2006 WL 2472484 (N.D. Cal., August
 24, 2006) (Bextra decision);

25 39. Plaintiffs allege that GSK failed to disclose certain risks of Avandia. *See*
 26 *e.g.*, Cosner Decl. Exh. A, ¶ 44-46. This allegation necessarily requires Plaintiffs to
 27 establish that the FDA, which has exclusive jurisdiction over the labeling of drugs, would
 28 have approved the warning the Plaintiffs allege should have been given.

1 40. Accordingly, there is a substantial federal question with respect to whether
 2 Plaintiffs can claim that GSK violated state law in light of the FDA's control of
 3 Avandia's labeling and warning and its position on conflict preemption.

4 **C. The Federal Interest In Providing A Forum**

5 41. The federal government has a strong interest in having a federal court
 6 decide several of the issues in this case. Among these issues are:

- 7 a. whether any conduct of GSK violated any federal laws or
 8 regulations related to the labeling and marketing of Avandia; and
 9 b. whether the FDA-approved Avandia label was false and misleading,
 10 as alleged by Plaintiff, and whether a state may impose liability on
 11 GSK for not providing more information regarding alleged risks, as
 12 Plaintiff contends GSK should have done.

13 42. Plaintiffs' claims may be vindicated or defeated only by construction of
 14 federal statutes and regulations. The availability of a federal forum to protect the
 15 important federal interests at issue is therefore consistent with *Grable*, and determination
 16 by a federal court of the substantial and disputed federal issues that lie at the heart of this
 17 case would not "disturb any congressionally approved balance of federal and state
 18 judicial responsibilities." *Grable*, 125 S. Ct. at 2368.

19 **IV. CONFORMANCE WITH PROCEDURAL REQUIREMENTS**

20 43. This Court has jurisdiction over this matter based on federal question and
 21 diversity of citizenship, and the present lawsuit may be removed from the Superior Court
 22 of the State of California for the County of San Francisco, and brought before the United
 23 States District Court for the Northern District of California pursuant to 28 U.S.C. §§
 24 1331, 1332 and 1441.

25 44. Neither GSK nor McKesson have been served with Plaintiffs' Complaint.
 26 Cosner Decl. ¶9. Therefore, this Removal has been timely filed. *See* 28 U.S.C. §
 27 1446(b).

28 45. Since neither GSK nor McKesson have been "properly joined and served"

1 at the time of filing this Removal, GSK is entitled to removal under the plain language of
 2 28 U.S.C. § 1441(b). *See Waldon v. Novartis Pharmaceuticals Corp.*, 2007 U.S. Dist.
 3 LEXIS 45809 (N.D. Cal. June 18, 2007). *See also* 28 U.S.C. § 1441(b); Cosner Decl. ¶9.

4 46. McKesson's consent to remove is not necessary because it is fraudulently
 5 joined. *See* Cosner Decl. Exh. D, ¶ 5. *See also*, e.g., *Easley v. 3M Company, et al.*, 2007
 6 WL 2888335 (N.D. Cal. 2007) *citing Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1193
 7 n.1 (9th Cir. 1988).

8 47. The United States District Court for the Northern District of California is
 9 the federal judicial district encompassing the Superior Court of the State of California for
 10 the County of San Francisco, where this suit was originally filed. Venue therefore is
 11 proper in this district under 28 U.S.C. § 1441(a).

12 48. Pursuant to the provisions of 28 U.S.C. § 1446(d), GSK will promptly file a
 13 copy of this Notice of Removal with the clerk of the Superior Court of the State of
 14 California for the County of San Francisco, where this suit was originally filed.

15 49. Defendant reserves the right to amend or supplement this Notice of
 16 Removal.

17 **WHEREFORE**, GSK respectfully removes this action from the Superior Court of
 18 the State of California for the County of San Francisco to the United States District Court
 19 for the Northern District of California, pursuant to 28 U.S.C. § 1441.

20 Dated: May 27 2008

21 DRINKER BIDDLE & REATH LLP

22 
 23 KRISTA L. COSNER

24 Attorneys for Defendant
 25 SMITHKLINE BEECHAM
 26 CORPORATION d/b/a
 27 GLAXOSMITHKLINE